Remarks

The Office action mailed May 1, 2007, has been reviewed and carefully considered. Claim 28 has been amended. Previously pending claims 30-34 have been canceled. Entry of these amendments is respectfully requested.

35 U.S.C. §112, second paragraph, rejections

Claims 21-23 have been rejected for alleged indefiniteness regarding the terms "flow," "cannula," and "rate." Claims 21 -23 are dependent claims based on claim 1. The purpose of these dependent claims is to claim certain optional features of the method. In other words, the features noted by the examiner are additional optional elements of the method of claim 1. Since these are optional features that are claimed dependently there is no need to include these features in base claim 1. Moreover, none of these features are preceded by the article "the." Thus, there is no need to provide antecedent basis in claim 1. Accordingly, the 35 U.S.C. §112, second paragraph, rejection of claims 21-23 must be withdrawn.

Claim 28 has been amended to specify that the imaging moiety is conjugated to the therapeutic agent of claim 26.

35 U.S.C. §102 rejections

Claims 1-5, 25, 26, 27 and 30 have been rejected under 35 U.S.C. §102 over Laske et al. The method of claim 1 includes providing a solution comprising a therapeutic agent *and* a tracer, and monitoring a distribution of the solution *during delivery* by imaging the tracer. The method of independent claim 26 includes delivering a solution comprising a therapeutic agent *and* a tracer, and monitoring a distribution of the tracer by MRI or CT as it moves through the target tissue.

The Office action on page 3 states that "it appears that Laske et al. used a tracer (Gd; claims 5,30) with the therapeutic agent Tf-CRM107 to monitor the distribution of the solution in the brain (claims 25,27) by imaging via MRI (claim 4) the tracer (claim 1), and ceased the delivery when the volume reached 40ml (claim 2,26)at the target tissue (claim 3)." In support of

this position, the Office action cites Table 2, footnote 1, of the Laske et al. article which states that "Tf-CRM107 concentration was initially kept constant at 0.1 μg/ml while the volume was escalated to 40 ml to improve drug distribution as assessed by MRI (volume of necrosis and infusion edema)." Attached is a Declaration of Dr. Edward Oldfield under 37 C.F.R. §1.132 explaining Laske et al. does not, in fact, disclose the method of claims 1 or 26 (Dr. Oldfield is a co-inventor of the present application and a co-author of Laske et al.).

According to Dr. Oldfield, a solution that included both Tf-CRM107 *and* Gd was not administered during the studies reported in Laske et al. Thus, the method performed in the Laske et al. study did not include providing or delivering a solution comprising a therapeutic agent *and* a tracer as recited in claims 1 and 26. Moreover, MRI was performed *after* infusion of Tf-CRM107 rather than during infusion. The MRI was performed to assess tumor growth. Thus, the method performed in Laske et al. did not include monitoring a distribution of the solution *during delivery* by imaging the tracer as recited in claims 1 and 26.

It is respectfully submitted that the present application is in condition for allowance. Should there be any questions regarding this application, examiner Carlson is invited to contact the undersigned attorney at the telephone number shown below.

Respectfully submitted,

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